PhRMA
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January 15, 2016

Mr. Angelo J. Bellomo
Director of Environmental Health
Los Angeles County Department of Public Health
Sent via email to abellomo@ph.lacounty.gov and EPR@lacounty.gov

Dear Mr. Bellomo:

I am writing on behalf of the Pharmaceutical Research and Manufacturers of America (PhRMA) regarding the final drug take back ordinance. The biopharmaceutical industry in the United States remains committed to working with multiple stakeholders to help address issues associated with adhering to prescription medicines and prescription drug abuse.

We appreciated the opportunity to engage with the County and relevant stakeholders over the past few months on these important issues. However, we are disappointed that despite our forthcoming and thorough input and cooperation in this initial phase and drafting process, the final ordinance appears to be nothing but a carbon-copy of the flawed and still not fully implemented Alameda County Ordinance.

Despite the guiding principles underlying this entire process, the final ordinance only implicates the manufacturing community and does not include requirements for any other stakeholders in the drug supply chain, and the ordinance will not be easily or effectively implemented, as seen in Alameda which still has not operationalized ongoing collection, and will not have any meaningful impact on environmental or drug abuse concerns.

PhRMA is a voluntary, nonprofit organization representing the country's leading research-based pharmaceutical and biotechnology companies, which are devoted to inventing medicines that allow patients to lead longer, healthier, and more productive lives. PhRMA companies are leading the way in the search for cures. Innovative medicines, such as those developed by PhRMA's members, account for approximately 10 to 15% of the prescription medicines filled in Los Angeles County – the rest are generic medicines.

As discussed during the stakeholder meetings and in previous letters, we again reassert our significant and science-based concerns and opposition to an "Alameda-like" ordinance, even if revised. We have highlighted the myriad complications associated with the disposal of unused medicines outside of the otherwise broadly recommended household trash method. These complexities play a significant role in the establishment of such a product take-back program and have resulted in a severely limited program in Alameda – not to mention a substantial and unnecessary price tag.

As we have consistently stated, regardless of legislative tweaks, PhRMA fundamentally opposes mandates to take back unused pharmaceutical products. Our opposition is hinged on the fact that these programs will not work, again as seen in Alameda, and will not address environmental concerns or drug abuse. It is the prescribers and the insurers that decide the amount of medicine a person is prescribed and can purchase.

Our main areas of concern with the final ordinance as drafted are incorporated below:

Alameda: A Fundamentally Flawed Program:

The final ordinance is almost a carbon copy of the County of Alameda's unsuccessful drug take back program, with the addition of several other harmful provisions. As seen in Alameda, the drug take back program will be severely limited because of the rigorous safety standards necessary to comply with the necessary regulations issued by the U.S. Drug Enforcement Administration (DEA). In fact, kiosk collection in Alameda has yet to commence. Per the DEA regulations, any kiosk-based take-back program that will or could reasonably be expected to collect controlled substances will need to be located at only a handful of regulated sites.

Specifically, law enforcement offices, pharmacies, certain hospitals with pharmacies, long term care facilities, and pharmaceutical manufacturers (but regulations only allow manufacturers to collect at their physical DEA registered locations). It is important to note, however, that during the open meetings in Los Angeles, as recently as last month, representatives from the pharmacy community indicated a disinterest in hosting kiosks.

This difficulty in securing community-wide kiosk locations is evident in Alameda as well. And for good reason: kiosks are necessarily a collection point – a very visible one – for prescription medications. Unfortunately, this also makes them a target for diversion, so we understand why pharmacies do not want to take on this liability. This is why recommendations for in-home disposal, as is widely accepted throughout the healthcare system, is so attractive.

In-home disposal has the dual advantage of not amassing a publicly accessible collection of prescription medicines, but it also makes the entire process intuitive and accessible to the widest range of consumers. Moreover, such a disposal method avoids the regulatory complexities of a program that must comply with multiple state and federal regulations.

DEA Regulations:

The final ordinance completely fails to recognize the complexities of the DEA regulations. Take-back programs, whether industry funded or not, are regulated by the DEA if they collect, or may reasonably be expected to collect, controlled substances. In programs that contain consumer-facing collection, it is a virtual certainty that consumers will deposit controlled substances, thus triggering the oversight of the DEA. And, to be sure, even if there is an explicit warning to not deposit controlled substances, the DEA regulations apply even if these products are *inadvertently* returned.[1]

Since no collection program will be able to be monitored at all times, any realistic program will need to operate in compliance with DEA regulations to ensure complete protection from inadvertent controlled substance liabilities.

Like the program in Alameda, simply shifting the funding and coordination activities of such a take-back program on to industry does not mitigate the responsibilities for compliance of the local pharmacies and law enforcement agencies that might serve as hosts for these kiosks. In fact, the DEA rules prohibit the mitigation of a pharmacy's regulatory burden by having a distributor or other entity maintain the collection receptacle at the subject pharmacy for them; thus the likely opposition to hosting kiosks by the pharmacy community during the stakeholder meetings.

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[1] *See* 79 Fed. Reg. 5320, 5329 (Sept. 9, 2014) ("[A]ll [DEA] regulations and laws relevant to controlled substances will apply if controlled substances are collected, even if inadvertently.").

Cost:

Placing new, considerable, mandated cost pressures on the industry is inconsistent with the shared goal of keeping medicine affordable. It is unavoidable that the legislation's mandates will lead to substantial costs that will eventually impact a manufacturer's cost of doing business—resulting in higher drug prices for everyone.

This ordinance includes fees, penalties, and other mandated costs that will unquestionably result in higher prices for prescription and non-prescription medications across the United States. Not only are manufacturers required to cover all the costs associated with administering, operating, collecting, transporting, and disposing of returned products, but companies are likewise required to cover the costs borne by the County in administering and enforcing the provisions of the program itself.

Sharps:

PhRMA strongly opposes take back mandates for drugs ***and*** sharps. It is already illegal for people to throw their sharps in the garbage in California. Unfortunately, illicit drug use is also a significant source of sharps in the waste stream and a sharps disposal mandate would not solve this issue. No matter what, those who handle municipal waste will need to protect themselves from any item in the waste stream that could puncture or cut their protective gear, including sharps used by users of illicit drugs. The envisioned program will likely not impact this waste stream.

In California, there is significant existing infrastructure to help patients dispose of their used sharps. For example, there are both public and private sector solutions available to consumers. Patients can access a list of 616 sites on www.calrecycle.gov to dispose of their used sharps. Some jurisdictions offer 'at your door' or curbside pickup for sharps as well.

Additionally, there are existing requirements for the sharps industry in California. That includes providing materials on safe disposal in the packaging inserts that come with their medicine, maintaining a call center to help patients with questions on disposal and posting information on their websites.

In addition to many sites for disposal currently available in California, a recent study by the University of California, Berkeley entitled "Infection Risk from "Sharps" Injuries for Non-healthcare Workers" for the Commission on Health and Safety and Workers Compensation in March of 2015 found that "needlestick injuries in non-healthcare settings are uncommon and the risk from any needlestick resulting in chronic disease is very small...**We find no evidence that additional statutory and regulatory action covering home-health sharps waste or sharps injuries to non-healthcare workers is warranted."**[2]

Specifically they report that:

- A review of research literature on non-healthcare, occupational sharps injuries found an extremely small number of confirmed cases of either HIV of HCV being transmitted by needlestick injuries outside healthcare settings. The combined number in developed, western countries appears to be less than 10 total for all countries from the onset of the AIDS epidemic through 2008.

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[2] Neuhauser, F., Shor, G., & Jackson, R. (2015). "Infection Risk from 'Sharps' Injuries for Non-healthcare Workers." University of California, Berkeley

- An analysis of the research on the mechanism of transmission was consistent with the findings of very few cases. We estimate that the risk of HIV from a work related needlestick injury converting to an HIV infection was 1/1 million to 75/1 million when the needle was from an intravenous (IV) drug user. For home-health sourced waste, the risk of infection may be as small as 1/100 million needlesticks.

- A review of data from the Division of Workers' Compensation Information System found that needlestick injuries were uncommon. In non-healthcare settings, approximately 1/10,000 workers will experience a needlestick injury in any year. These numbers are higher in specific industries and occupations, but still in the area of 1/1,000 workers per year.
- Prophylactic treatment after needlesticks, a measure of the risk perceived by healthcare providers and patients, is also infrequent. Only 1.2% of these injuries received prophylactic treatment.

Educating the patient on the proper collection and disposal of home generated sharps is one of the most important ways to ensure that needlestick injury exposure is minimized. A patient's first source of information should be the physician prescribing the self-injected medicine. The physician, nurse or other healthcare provider should instruct the patient on how to inject the medicine as well as how to properly dispose of the sharp once it has been used. The type of product and how it is injected will determine the most appropriate disposal method for that particular patient.

Pharmaceutical companies provide patient support information first, though the prescribing physician and then directly to the patient through prescription package inserts, websites, brochures, videos, or 1-800 numbers. The industry partners with healthcare providers to ensure that education pertaining to home generated sharps use and disposal is delivered efficiently and in a manner that each individual patient can understand.

PhRMA member companies have worked to develop safe, convenient and cost-effective methods for disposing of used sharps. During the development of innovative home-injectable medicines, pharmaceutical companies strive to employ safe needle technologies which will protect patients and those assisting in the disposal of used sharps. In fact, some injection devices are designed to retract or shield the needle. Other types of injectable products utilize a needle cap that locks in place when attaching the needle prior to injection or for safe disposal.

Mail-back Programs: Increased Risk of Diversion:

The final ordinance includes a mail-back option for all residents to return unused medicines. PhRMA has serious concerns about the high likelihood of diversion that could occur with drug mail-back programs. Further, such a program is unquestionably the costliest and least efficient alternative.

Currently, there are mechanisms in place to secure medicines in the supply chain moving from manufacturers to the patient, but a reverse system to secure medicines from the patients back through the mail does not exist. For example, mail-back programs do not have a completely secure way to track medicines sent from the patient to a DEA-compliant facility. It is reasonable to expect that drug take-back mailers would be targets for those wishing to divert medicines for misuse and abuse. Additionally, DEA requires on-site and immediate destruction of mailed-back packages. Presently, our research has not identified such a certified facility in the US.

Finally, both of these proposed programs ignore the real goal underlying the idea of take-back: minimizing the possibilities that unused medicines meet an undesirable end. Nothing suggests that consumers will actually use such programs, and, in fact, much evidence cuts in the opposite direction.

An Alternative for Safe and SecureDisposal of Unused Medicines: In-Home Secure Disposal

Instead of implementing a flawed, unsuccessful program, we urge the County to consider meaningful, measurable and comprehensive mechanisms to educate consumers on how to safeguard medicines in the home, how to ensure patients are taking their medicines as prescribed – thereby significantly mitigating unused medicines in the first place – and how to safely and securely dispose of their truly unused medicines in the household trash.

Research demonstrates that household trash disposal is effective for disposing of unused medicines. For many, in-home medicine disposal offers a simple, convenient way to dispose of unwanted, unneeded or expired medication. Because all households already participate in the collection of household trash, in-home drug disposal is a safe and preferred way of disposing of unused, unwanted or unneeded medicine.

In-home medicine disposal offers many benefits. It removes the medicines from the home immediately so that the medicine is not available for misuse or abuse and it does not create any additional environmental impact or cost. It also gives community members the ability to handle medicine disposal discretely and independently, and protects medical privacy when done properly.

In-home disposal effectively manages any potential environmental issues given that household waste in the U.S. is either incinerated or disposed of in capped, double-lined landfills equipped with leachate collection and treatment systems. Either technology effectively isolates waste from the physical environment. In-home disposal also avoids the environmental carbon footprint and costs of trips to a collection site and of separately shipping the collected pharmaceuticals for destruction.

PhRMA believes that any stakeholder approach in Los Angeles County should focus on educating patients on how to securely dispose of unused pharmaceutical products. A potential model for the county could be PhRMA's "MyOldMeds" Program (http://myoldmeds.com), which we have successfully piloted in New York. This program instructs patients on how to safely dispose of medicine in the home or where to find current take back programs in their community. To safely dispose of medicines in the home, PhRMA recommends these easy steps:

- Step 1: Pour medication into a sealable plastic bag. If the medication is in solid form (pill, liquid capsule, etc.), add water to dissolve it.
- Step 2: Add kitty litter, sawdust, coffee grounds or another mixing material to the plastic bag to make the solution less appealing for pets and children.
- Step 3: Seal the plastic bag and put it in the trash.
- Step 4: Remove and destroy all identifying personal information (for example, the prescription label) from the medication containers before recycling them or throwing them away. This helps to ensure medical privacy.

Based on the success of the pilot program in New York, we know that educating consumers on safely storing and disposing of medicines in their own home works. The industry would like the opportunity to expand on those efforts in Los Angeles County and is committed to working with the County on such efforts.

In conclusion, PhRMA recommends that the County focus their efforts on promoting adherence to medication treatment regimens and educating their constituents on the safe disposal of unused medicines. As the County discusses the important public health issues of adherence to prescription drug medicines, secure disposal of unused medicines, and prescription drug abuse, the biopharmaceutical industry is committed to working with

multiple stakeholders to help address these issues. We look forward to continue engaging with you to assess opportunities for you and the residents of your County.

Sincerely,

Marissa Watkins
Director, State Advocacy
The Pharmaceutical Research and Manufacturers of America

Cc: Office of Supervisor Hilda Solis - Jo-Ann Yanagimoto-Pinedo and Teresa Villegas
Office of Supervisor Mark Ridley-Thomas - Michael Hochman and Yolanda Vera
Office of Supervisor Sheila Kuehl - Maria Chong-Castillo and Elan Shultz
Office of Supervisor Don Knabe - Rick Velasquez and Richard Espinosa
Office of Supervisor Mike Antonovich - Kathryn Barger, Fred Leaf and Edel Vizcarra

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November 20, 2015

Mr. Angelo J. Bellomo
Director of Environmental Health
Los Angeles County Department of Public Health
Sent via email to abellomo@ph.lacounty.gov and EPR@lacounty.gov

Dear Mr. Bellomo:

I am writing on behalf of the Pharmaceutical Research and Manufacturers of America (PhRMA) regarding the draft drug take back ordinance. The biopharmaceutical industry in the United States is committed to working with multiple stakeholders to help address issues associated adhering to prescription medicines and prescription drug abuse. We appreciated the opportunity to engage with the County and relevant stakeholders over the past few months on these important issues. We are disappointed, however, that despite our thorough and up-front input and cooperation in this initial phase, the draft ordinance appears to be nothing but a carbon-copy of the flawed and still not fully implemented Alameda County Ordinance. Thus, despite the guiding principles underlying this entire process, the draft ordinance does not encompass any drug supply chain stakeholders except the manufacturing community, will not be easily or effectively implemented, and will not have any meaningful impact on environmental or drug abuse concerns.

PhRMA is a voluntary, nonprofit organization representing the country's leading research-based pharmaceutical and biotechnology companies, which are devoted to inventing medicines that allow patients to lead longer, healthier, and more productive lives. PhRMA companies are leading the way in the search for cures. Innovative medicines, such as those developed by PhRMA's members, account for approximately 10 to 15% of the prescription medicines filled in Los Angeles County – the rest are generic medicines.

As discussed during the stakeholder meetings and in previous letters, we again reassert our significant and science-based concerns and opposition to an "Alameda-like" ordinance, even if revised. We have highlighted the myriad complications associated with the disposal of unused medicines outside of the otherwise broadly recommended household trash method. These complexities play a significant role in the establishment of such a product take-back program and have resulted in a severely limited program in Alameda – not to mention a substantial and unnecessary price tag. As we have consistently stated, regardless of legislative tweaks, PhRMA fundamentally opposes mandates to take back unused pharmaceutical products. Our opposition is hinged on the fact that these programs will not work and will not address environmental concerns or drug abuse. It is the prescribers and the insurers that decide the amount of medicine a person is prescribed and can purchase.

Our main areas of concern with the draft ordinance are incorporated below:

Alameda: A Fundamentally Flawed Program:

The draft ordinance is almost a carbon copy of the County of Alameda's unsuccessful drug take back program, with the additional of several other harmful provisions. As seen in Alameda, the drug take back program will be severely limited because of the rigorous safety standards necessary to comply with the necessary regulations issued by the U.S. Drug Enforcement Administration (DEA). In fact, kiosk collection in Alameda has yet to commence. Per those regulations, any kiosk-based take-back program that will or could reasonably be expected to collect controlled substances will need to be located at only a handful of regulated sites. Specifically, law

enforcement offices, pharmacies, certain hospitals with pharmacies, long term care facilities, and pharmaceutical manufacturers (but only at their physical DEA registered locations). It is important to note, however, that during the open meetings in Los Angeles, as recently as last month, representatives from the pharmacy community indicated a disinterest in hosting kiosks.

This difficulty in securing community-wide kiosk locations is evident in Alameda as well. And for good reason: kiosks are necessarily a collection point – a very visible one – for prescription medications. Unfortunately, this also makes them a target for diversion and we understand why pharmacies do not want to take on this liability. This is why recommendations for in-home disposal, as is widely accepted throughout the healthcare system, is so attractive. In-home disposal has the dual advantage of not amassing a publicly accessible collection of prescription medicines, but it also makes the entire process intuitive and accessible to the widest range of consumers. Moreover, such a disposal method avoids the regulatory complexities of a program that much comply with multiple state and federal regulations.

DEA Regulations:

The draft ordinance completely fails to recognize the complexities of the DEA regulations. Take-back programs, whether industry funded or not, are regulated by the DEA if they collect, or may reasonably be expected to collect, controlled substances. In programs that contain consumer-facing collection, it is a virtual certainty that consumers will deposit controlled substances, thus triggering the oversight of the DEA. And, to be sure, even if there is an explicit warning to not deposit controlled substances, the DEA regulations apply even if these products are *inadvertently* returned.[1] Since no collection program will be able to be monitored at all times, any realistic program will need to operate in compliance with DEA regulations to ensure complete protection from inadvertent controlled substance liabilities.

Like the program in Alameda, simply shifting the funding and coordination activities of such a take-back program on to industry does not mitigate the responsibilities for compliance of the local pharmacies and law enforcement agencies that might serve as hosts for these kiosks. In fact, the DEA rules prohibit the mitigation of a pharmacy's regulatory burden by having a distributor or other entity maintain the collection receptacle at the subject pharmacy for them; thus the likely opposition to hosting kiosks by the pharmacy community during the stakeholder meetings.

Cost:

Placing new, considerable, mandated cost pressures on the industry is inconsistent with the shared goal of keeping medicine affordable. It is unavoidable that the legislation's mandates will lead to substantial costs that will eventually impact a manufacturer's cost of doing business—resulting in higher drug prices for everyone.

This ordinance includes fees, penalties, and other mandated costs that will unquestionably result in higher prices for prescription and non-prescription medications across the United States. Not only are manufacturers required to cover all the costs associated with administering, operating, collecting, transporting, and disposing of returned products, but companies are likewise required to cover the costs borne by the County in administering and enforcing the provisions of the program itself.

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[1] *See* 79 Fed. Reg. 5320, 5329 (Sept. 9, 2014) ("[A]ll [DEA] regulations and laws relevant to controlled substances will apply if controlled substances are collected, even if inadvertently.").

Finally, and perhaps most objectionably, the draft ordinance contains a third-party enforcement provision. A provision that virtually ensures a costly bounty-hunter lawsuit brought against not just manufacturer funders of the program, but very likely against community pharmacy hosts of any kiosks. This is extremely concerning and goes beyond Alameda language.

Sharps:

PhRMA strongly opposes take back mandates for drugs ***and*** sharps. It is already illegal for people to throw their sharps in the garbage in California. Unfortunately, illicit drug use is also a source of sharps in the waste stream and a sharps disposal mandate would not solve this issue.

In California, there is significant existing infrastructure to help patients dispose of their used sharps. There are both public and private sector solutions available to consumers. Patients can access a list of 616 sites on www.calrecycle.gov to dispose of their used sharps. Some jurisdictions offer 'at your door' or curbside pickup for sharps as well.

Additionally, there are existing requirements for the sharps industry in California. That includes providing materials on safe disposal in the packaging inserts that come with their medicine, maintaining a call center to help patients with questions on disposal and posting information on their websites.

Educating the patient on the proper collection and disposal of home generated sharps is one of the most important ways to ensure that needle stick injury exposure is minimized. A patient's first source of information should be the physician prescribing the self-injected medicine. The physician, nurse or other healthcare provider instructs the patient on how to inject the medicine as well as how to properly dispose of the sharp once it has been used. The type of product and how it is injected will determine the most appropriate disposal method for that particular patient.

Pharmaceutical companies provide patient support information first, though the prescribing physician and then directly to the patient through prescription package inserts, websites, brochures, videos, or 1-800 numbers. The industry partners with healthcare providers to ensure that education pertaining to home generated sharps use and disposal is delivered efficiently and in a manner that each individual patient can understand.

PhRMA member companies have worked to develop safe, convenient and cost-effective methods for disposing of used sharps. During the development of innovative home-injectable medicines, pharmaceutical companies strive to employ safe needle technologies which will protect patients and those assisting in the disposal of used sharps. In fact, some injection devices are designed to retract or shield the needle and are inherently safer than a syringe. Other types of injectable products utilize a needle cap that locks in place when attaching the needle prior to injection or for safe disposal.

Incentives for Participation are Highly Illegal:

The Draft Ordinance makes mention that manufacturer take-back plans can provide incentives to pharmacies to host kiosk sites. The Federal Anti-Kickback Statute, however, virtually guarantees that no pharmaceutical manufacturer would provide such an incentive.[2] This provision of federal law generally prohibits remuneration to induce or reward patient referrals or for the generation of business involving any item or service payable by federal healthcare programs. This statute is broadly interpreted and aggressively enforced. As such, most

[2] 42 U.S.C. § 1320a-7b(b).

conservative compliance programs steadfastly discourage general "incentive" payments to providers and pharmacies in order to avoid even the appearance of a possibly disguised payment that may trigger Anti-Kickback scrutiny. As such, incentive payments to pharmacies would simply not occur.

Finally, and perhaps most objectionably, the draft ordinance contains a third-party enforcement provision. A provision that virtually ensures a costly bounty-hunter lawsuit brought against not just manufacturer funders of the program, but very likely against community pharmacy hosts of any kiosks.

Mail-back Programs: Increased Risk of Diversion:

The draft ordinance includes a mail-back option for all residents to return unused medicines. PhRMA has serious concerns about the high likelihood of diversion that could occur with drug mail-back programs. Further, such a program is unquestionably the costliest and least efficient alternative.

Currently, there are mechanisms in place to secure medicines in the supply chain moving from manufacturers to the patient, but a reverse system to secure medicines from the patients back through the mail does not exist. For example, mail-back programs do not have a completely secure way to track medicines sent from the patient to a DEA-compliant facility. It is reasonable to expect that drug take-back mailers would be targets for those wishing to divert medicines for misuse and abuse. Additionally, DEA requires on-site and immediate destruction of mailed-back packages. Presently our research has not identified such a certified facility in the US.

Finally, both of these proposed programs ignore the real goal underlying the idea of take-back: minimizing the possibilities that unused medicines meet an undesirable end. Nothing suggests that consumers will actually use such programs, and, in fact, much evidence cuts in the opposite direction.

Alternative Successful Program: In-Home Disposal

Instead of implementing a flawed, unsuccessful program, we urge the County to consider meaningful, measurable and comprehensive mechanisms to educate consumers on how to safeguard medicines in the home, how to ensure patients are taking their medicines as prescribed – thereby significantly mitigating unused medicines in the first place – and how to safely and securely dispose of their truly unused medicines in the household trash.

Research demonstrates that household trash disposal is effective for disposing of unused medicines. For many, in-home medicine disposal offers a simple, convenient way to dispose of unwanted, unneeded or expired medication. Because all households already participate in the collection of household trash, in-home drug disposal is a safe and preferred way of disposing of unused, unwanted or unneeded medicine.

In-home medicine disposal offers many benefits. It removes the medicines from the home immediately so that the medicine is not available for misuse or abuse and it does not create any additional environmental impact or cost. It also gives community members the ability to handle medicine disposal discretely and independently, and protects medical privacy when done properly.

In-home disposal effectively manages any potential environmental issues given that household waste in the U.S. is either incinerated or disposed of in capped, double-lined landfills equipped with leachate collection and treatment systems. Either technology effectively isolates waste from the physical environment. In-home disposal also avoids the environmental carbon footprint and costs of trips to a collection site and of separately shipping the collected pharmaceuticals for destruction.

PhRMA believes that any stakeholder approach in Los Angeles County should focus on educating patients on how to securely dispose of unused pharmaceutical products. A potential model for the county could be PhRMA's "MyOldMeds" Program (http://myoldmeds.com), which we have successfully piloted in New York. This program instructs patients on how to safely dispose of medicine in the home or where to find current take back programs in their community. To safely dispose of medicines in the home, PhRMA recommends these easy steps:

- Step 1: Pour medication into a sealable plastic bag. If the medication is in solid form (pill, liquid capsule, etc.), add water to dissolve it.
- Step 2: Add kitty litter, sawdust, coffee grounds or another mixing material to the plastic bag to make the solution less appealing for pets and children.
- Step 3: Seal the plastic bag and put it in the trash.
- Step 4: Remove and destroy all identifying personal information (for example, the prescription label) from the medication containers before recycling them or throwing them away. This helps to ensure medical privacy.

Based on the success of the pilot program in New York, we know that educating consumers on safely storing and disposing of medicines in their own home works. The industry would like the opportunity to expand on those efforts in Los Angeles County and is committed to working with the County on such efforts.

In conclusion, PhRMA recommends that the County focus their efforts on promoting adherence to medication treatment regimens and educating their constituents on the safe disposal of unused medicines. As the County discusses the important public health issues of adherence to prescription drug medicines, secured disposal of unused medicines, and prescription drug abuse, the biopharmaceutical industry is committed to working with multiple stakeholders to help address these issues. We look forward to continue engaging with you to assess opportunities for you and the residents of your County.

Sincerely,

Marissa Watkins

Marissa Watkins
Director, State Advocacy
The Pharmaceutical Research and Manufacturers of America

Cc: Health Deputy Jo-Ann Yanagimoto-Pinedo, Office of Supervisor Hilda Solis
Senior Deputy for Healthcare Services Yolanda Vera, Office of Supervisor Mark Ridley-Thomas
Health Deputy Elan Shultz, Office of Supervisor Sheila Kuehl
Health Deputy Richard Espinosa, Supervisor Don Knabe
Senior Health Deputy Fred Leaf, Office of Supervisor Mike Antonovich

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October 26, 2015

Mr. Angelo J. Bellomo
Director of Environmental Health
Los Angeles County Department of Public Health
Sent via email to abellomo@ph.lacounty.gov and EPR@lacounty.gov

Dear Mr. Bellomo:

I am writing on behalf of the Pharmaceutical Research and Manufacturers of America (PhRMA) regarding the "Objective, Proposed Goals, and TAG Purpose" document released before the October 14 Technical Advisory Group Meeting. We appreciate the opportunity to participate in these meetings and provide comments on the Objectives below.

PhRMA is a voluntary, nonprofit organization representing the country's leading research-based pharmaceutical and biotechnology companies, which are devoted to inventing medicines that allow patients to lead longer, healthier, and more productive lives. PhRMA companies are leading the way in the search for cures. Innovative medicines, such as those developed by PhRMA's members, account for approximately 10 to 15% of the prescription medicines purchased in Los Angeles County – the rest are generic medicines.

As discussed during both meetings, we again assert our significant and science-based concerns with an "Alameda-like" ordinance. We also want to highlight the myriad complications associated with the disposal of unused medicines outside of the otherwise broadly recommended household trash method. These complexities play a significant role in the establishment of a product take-back program and have resulted in an Alameda significantly limiting its program – not to mention a significant and unnecessary price tag, which will raise the industry's cost of doing business at a time when there is significant concern with the cost of healthcare in the United States.

Below, please find our feedback on the document:

1. ***Objective: Ensure all County residents have access to safe, convenient, and sustainably financed take-back options for properly disposing unwanted pharmaceutical and sharps waste.***

   PhRMA Comments:

   - It is important to understand the regulatory and legal issues associated with such programs which will limit access to a take back program.
     - Drug take-back programs are regulated by the U.S. Drug Enforcement Administration (DEA) if they collect, or may reasonably be expected to collect, controlled substances.
     - DEA compliance **is incumbent upon the take back program participants, not just its funders**. In other words, it will be the kiosk host sites that must carefully evaluate how and to what degree they want to participate and comply with DEA regulations since, ultimately, the responsibility to ensure compliance and monitor operations falls upon them.
     - Hosting a kiosk carries a multitude of location-selection, security, logistical, and reporting obligations on the kiosk host himself – things that cannot be off-loaded on a program funder or coordinator. This is a reality that Alameda simply chose to ignore under its Ordinance and now is forced to only have the program run at law enforcement locations.
     - Although PhRMA very much understands the pharmacy community's very real concerns with hosting kiosks, without robust participation from pharmacies, a drug and sharps take

back program will never be "convenient" because it will be limited to law enforcement locations that are already overwhelmed with this issue.

2. ***Program Goals***

   a. ***Promote extended producer responsibility principles which pertain to the proper management of products at the end of their useful life.***

      - **PhRMA Comments:** Pharmaceuticals are unlike other products for which EPR programs are established. Fundamentally, the goal of EPR is to reduce, recycle and reuse. Medicines cannot be recycled by law. Additionally, we encourage patients to take their medication as prescribed, which should result in minimal unused product, and to dispose of that medicine properly.

   b. ***These principles include but are not limited to: Creating a mechanism for shared logistical and financial responsibility for safe drug and sharp disposal programs***

      - **PhRMA Comments:** PhRMA has expressed our desire to work with the County of educating patients on how to dispose of their unused medicines properly. With respect to sharps, the State of California already requires our companies to post education about sharps disposal. Proper disposal as outlined by PhRMA and our member companies will mitigate waste and reduce financial responsibility for everyone. Also, it should be noted that PhRMA's members' products require a prescription, and given this, patients are limited to buying branded, prescription drugs in the type and quantity that is right for them. Any financial obligation should include **all stakeholders in the medicine supply chain, as well as the County requesting any such program—especially since a special program for drug waste in not needed and will not achieve the County's stated goals.**

   c. ***These principles include but are not limited to: Ensuring convenience for the public***

      - **PhRMA Comments**: As seen in Alameda, drug take back programs are severely limited because of the restrictions in place by the DEA regulation. Only law enforcement, pharmacies, hospitals and pharmaceutical manufacturers can register with the DEA to host kiosks on the site corresponding with the entity's DEA registration. Pharmacies have signed up to participate in the Alameda program and the burden will continue to fall on law enforcement. The program is not operating as envisioned and is not meeting the County's requirement that will likely be impossible to implement, for convenience.

   d. ***Develop a County program to administer mail-back programs and maintain collection receptacles, consistent with the Drug Enforcement Administration Disposal Act as stipulated within the framework of the Controlled Substances Act, and all other applicable Federal, State, and local laws and regulations.***

      - **PhRMA Comments:** There are serious concerns about the high likelihood of diversion that could occur with drug mail-back programs. Further, such a program is unquestionably the costliest and least efficient alternative. Currently, there are mechanisms in place to secure medicines in the supply chain moving from manufacturers to the patient, but a reverse system to secure medicines from the patients back through the mail does not exist. For example, mail-back programs do not have a completely secure way to track medicines sent from the patient to a DEA-compliant facility. It is reasonable to expect that drug take-back mailers would be targets for those wishing to divert medicines for misuse and abuse. Additionally, DEA requires on-site and immediate destruction of mailed-back packages. To our knowledge, there is no such certified facility in the US. Finally, both of these proposed programs ignore the real goal underlying the idea of take-back: minimizing the possibilities that unused medicines meet an undesirable end. Nothing suggests that consumers will actually use such programs, and, in fact, much evidence cuts in the opposite direction.

3. ***Technical Advisory Group (TAG) Purpose: Facilitate a constructive dialogue regarding potential components of a draft ordinance with stakeholders who will be directly impacted by the ordinance and Receive feedback on best practices of EPR programs for unwanted pharmaceuticals and sharps waste from around the world, including within California.***

PhRMA Response: There are no best practices from existing programs in California. Alameda is significantly limited because of federal law and regulations and programs in other countries are not a good comparison given the vastly different health care delivery systems and federal and state governing law.

- It is important to note the different laws governing return of controlled substances internationally. In the U.S., a pharmacist cannot take-back a controlled medicine unless they are registered with the Drug Enforcement Agency (DEA) and they have established a wholly-compliant kiosk program under DEA's take-back regulations.
- If a pharmacy does not register, and a program similar to British Columbia's (BC's) is implemented, the pharmacist would have to individually screen each medicine being returned and only take back a non-controlled medicine—such a task would increase a pharmacy's costs by using pharmacist time to review each item being returned and reduce the amount of time they have to focus on patients.
- The BC program notes in its 2008 report that expired medicines do not pose a serious threat to public health and the medicines returned under the program would not meet requirements for hazardous waste; whereas, in the United States, aggregated medicines from a drug take back program must be treated as hazardous waste.
- The BC 2008 report also notes that pharmaceuticals are not significant by weight or volume to the waste stream [and is certainly not a significant volume of Los Angeles' waste stream].

As the County discusses the important public health issues of adherence to prescription drug medicines, secured disposal of unused medicines, and prescription drug abuse, the biopharmaceutical industry is committed to working with multiple stakeholders, including other entities in the drug supply chain, healthcare prescribers and pharmacists, to help address these issues, and we look forward to continue engaging with you to assess opportunities for you and the residents of your County.

Sincerely,

Marissa Watkins
Director, State Advocacy
The Pharmaceutical Research and Manufacturers of America

Cc: Health Deputy Jo-Ann Yanagimoto-Pinedo, Office of Supervisor Hilda Solis
Senior Deputy for Healthcare Services Yolanda Vera, Office of Supervisor Mark Ridley-Thomas
Health Deputy Elan Shultz, Office of Supervisor Sheila Kuehl
Health Deputy Richard Espinosa, Supervisor Don Knabe
Senior Health Deputy Fred Leaf, Office of Supervisor Mike Antonovich

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October 12, 2015

Mr. Angelo J. Bellomo
Director of Environmental Health
Los Angeles County Department of Public Health
Sent via email to abellomo@ph.lacounty.gov and EPR@lacounty.gov

Dear Mr. Bellomo:

I am writing on behalf of the Pharmaceutical Research and Manufacturers of America (PhRMA) regarding the stakeholder meeting on September 28. During the meeting, the Departments noted that it is their intent to draft an ordinance requiring manufacturers of prescription and non-prescription drugs and sharps to develop a product stewardship take-back program. Several issues were raised at the meeting about which we would like to provide additional information, including examples of Canadian take back programs and a mail back option. We appreciate the opportunity to participate in these meetings and provide additional comments.

PhRMA is a voluntary nonprofit organization representing the country's leading research-based pharmaceutical and biotechnology companies, which are devoted to inventing medicines that allow patients to lead longer, healthier, and more productive lives. PhRMA companies are leading the way in the search for cures. Innovative medicines, such as those developed by PhRMA's members, account for approximately 10 to 15% of the prescription medicines filled in Los Angeles County – the rest are generic medicines.

As discussed during the meeting, we again reassert our significant and science-based concerns with an "Alameda-like" ordinance. We also want to highlight the myriad complications associated with the disposal of unused medicines outside of the otherwise broadly recommended household trash method. These complexities play a significant role in the establishment of such a product take-back program and have resulted in a severely limited program in Alameda – not to mention a significant and unnecessary price tag.

In addition to the voluminous legal and regulatory hurdles associated with take-back programs, we also want to highlight for you the absolute dearth of scientific evidence linking both environmental impact and drug abuse to unwanted or unused prescription medicines. I've summarized below the findings of three reports that I've attached to the email that includes this letter. These studies include:

1. Landfill Disposal of Unused Medicines Reduces Surface Water Releases: This publication finds that the disposal of unused medications in municipal solid waste landfills effectively eliminates the unused medicine contribution of active pharmaceutical ingredients to surface waters and that more than 99.9% of what is disposed of in landfills are permanently retained (e.g., medicines are not leaching out of landfills). Lial Tischler, Mary Buzby, Douglas Finan, and Virginia L Cunningham in the *Integrated Environmental Assessment and Management Journal*
2. Life Cycle Comparison of Environmental Emissions from Unused Pharmaceutical Disposal Options: This peer-reviewed publication finds that the overall carbon footprint of a take-back program is environmentally more harmful because of the environmental effects of the collection, shipping, and disposal of the collected medicines. We raised this point at the

September 28 meeting because any drugs collected through either a state-wide program or county program would have to be shipped out-of-state to be incinerated in order to comply with federal law and regulations. Sherri Cook, Bryan VanDuinen, Nancy Love, and Steven Skerlos from the Department of Civil and Environmental Engineering, University of Michigan, Ann Arbor, Michigan in the *Environmental Science & Technology Journal* published by the American Chemical Society

3. Effects of Human Pharmaceuticals on Aquatic Life: Next Steps: This peer-reviewed publication finds that although some active pharmaceutical ingredients have been measured in drinking water, the scientific consensus is that pharmaceuticals at the low levels detected in the environment do not pose an appreciable risk to human health. It is important to remember that pharmaceuticals go through the Food and Drug Administration's rigorous testing for human safety and standards for potential environmental impact are considered as part of the FDA application. Virginia Cunnigham, GlaxoSmithKline; Mary Buzby Merck and Co., Inc.; Thomas Hutchinson, AstraZeneca; Frank Mastrocco Pfizer, Inc.; Neil Parke, Eli Lilly and Co.; Nicholas Roden, Schering-Plough Corp. in the *Environmental Science & Technology Journal* published by the American Chemical Society

Importantly, the Food and Drug Administration (FDA) finds that "the main way drug residues enter water systems is by people taking medicines and then naturally passing them through their bodies…many drugs are not completely absorbed or metabolized by the body and can enter the environment after passing through wastewater treatment plants. While FDA and the Environmental Protection Agency take the concerns of flushing certain medicines in the environment seriously, there has been no indication of environmental effects due to flushing."[1]

Differences between the British Columbia (BC) Program and U.S. Proposals

During both the September 28 morning and afternoon meetings, the British Columbia program was raised as an example of a take-back program. It is very important to note the different laws governing return of controlled substances in the two countries. In the U.S., a pharmacist cannot take-back a controlled medicine unless they are registered with the Drug Enforcement Agency (DEA) and they have established a wholly-compliant kiosk program under DEA's take-back regulations. If a pharmacy does not register, and a program similar to British Columbia's is implemented, the pharmacist would have to individually screen each medicine being returned and only take back a non-controlled medicine—such a task would increase costs by using pharmacist time to review each item being returned and reduce the amount of time they have to focus on patients. Additionally, the program likely would not reduce drug abuse as controlled substances are the drugs most abused and would not be collected.

The BC program notes in the 2008 report that expired medicines do not pose a serious threat to public health and the medicines returned under the program would not meet requirements for hazardous waste; whereas, in the United States, aggregated medicines from a drug take back program must be treated as hazardous waste. The BC 2008 report also notes that pharmaceuticals are not significant by weight or volume to the waste stream.

[1] Dr. Raanan Bloom, Ph.D. "How to Dispose of Unused Medicines" Food and Drug Administration http://www.fda.gov/ForConsumers/ConsumerUpdates/ucm101653.htm; 6/04/2015

Finally, and perhaps most importantly, the Canadian healthcare system in general is fundamentally different than the one in the United States. The Drug Enforcement Agency and Environmental Protection Agency, along with a host of federal and state laws, govern the disposal of unused medication in the United States. Canada has a completely different set of rules and governance over unused medicines, making the comparison between the two countries imbalanced. Additionally, as one can glean from the evidence in Alameda, which currently has absolutely no pharmacies participating in its program or anyone else willing to host a take-back kiosk, the Canadian healthcare model affords a different opportunity from governmental intervention.

Mail-back Programs: Increased Risk of Diversion

During the morning meeting, a participant raised the idea of requiring a mail-back program to return unused medicines. PhRMA has serious concerns about the high likelihood of diversion that could occur with drug mail-back programs. Further, such a program is unquestionably the costliest and least efficient alternative.

Currently, there are mechanisms in place to secure medicines in the supply chain moving from manufacturers to the patient, but a reverse system to secure medicines from the patients back through the mail does not exist. For example, mail-back programs do not have a completely secure way to track medicines sent from the patient to a DEA-compliant facility. It is reasonable to expect that drug take-back mailers would be targets for those wishing to divert medicines for misuse and abuse. Additionally, DEA requires on-site and immediate destruction of mailed-back packages. Presently our research has not identified such a certified facility in the US.

Finally, both of these proposed programs ignore the real goal underlying the idea of take-back: minimizing the possibilities that unused medicines meet an undesirable end. Nothing suggests that consumers will actually use such programs, and, in fact, much evidence cuts in the opposite direction.

Instead we urge the County to consider meaningful, measurable and comprehensive mechanisms to educate consumers on how to safeguard medicines in the home, how to ensure patients are taking their medicines as prescribed – thereby significantly mitigating unused medicines in the first place – and how to safely and securely dispose of their truly unused medicines in the household trash.

As the County discusses the important public health issues of adherence to prescription drug medicines, secured disposal of unused medicines, and prescription drug abuse, the biopharmaceutical industry is committed to working with multiple stakeholders, including other entities in the drug supply chain, healthcare prescribers and pharmacists, to help address these issues, and we look forward to continue engaging with you to assess opportunities for you and the residents of your County.

Sincerely,

Marissa Watkins
Director, State Advocacy
The Pharmaceutical Research and Manufacturers of America

Cc: Health Deputy Jo-Ann Yanagimoto-Pinedo, Office of Supervisor Hilda Solis

Senior Deputy for Healthcare Services Yolanda Vera, Office of Supervisor Mark Ridley-Thomas
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John A. Murphy, III
Assistant General Counsel

August 10, 2015

Dear Hon. Supervisors:

I am writing on behalf of the Pharmaceutical Research and Manufacturers of America (PhRMA) regarding the motion by Supervisor Antonovich and Supervisor Solis directing the Interim Chief Executive Officer to draft an ordinance requiring manufacturers of prescription and non-prescription drugs and sharps to develop a product stewardship take-back program.

PhRMA is a voluntary nonprofit organization representing the country's leading research-based pharmaceutical and biotechnology companies, which are devoted to inventing medicines that allow patients to lead longer, healthier, and more productive lives. PhRMA companies are leading the way in the search for cures. Innovative medicines developed by PhRMA's members account for approximately 10 to 15% of the prescription medicines filled in Los Angeles County.

On behalf of America's biopharmaceutical research and manufacturing organizations, we would like to provide some additional context surrounding the complications associated with the disposal of unused medicines, especially with respect to "Alameda-style" take-back programs. These complexities play a significant role in the establishment of such a product take-back program. In addition to the myriad legal and regulatory hurdles associated with these programs, we also want to highlight the lack of scientific evidence linking both environmental consequences and drug abuse to unwanted or unused prescription medicines.

As the County discusses the important public health issues of adherence to prescription medicines, secured disposal of unused medicines, and prescription drug abuse, the biopharmaceutical industry is committed to working with multiple stakeholders, including other entities in the drug supply chain, healthcare prescribers and pharmacists, to help address these issues. We believe that a collaborative approach, where the County engages all stakeholders that could be impacted by the proposed take-back program before an ordinance is drafted, is the best approach. We look forward to engaging with you to assess opportunities for you and the residents of your County.

Complexities of Drug Take-Back Programs

The concept of prescription drug take-back is not new, nor is there any new scientifically-validated evidence that has arisen over the past few years that has in any way validated or hastened the societal need for such programs. In fact, most evidence points in the opposite direction: showing that many already-operating prescription drug take-back programs are themselves far more burdensome to the environment than the leftover products they seek to pick-up (In the case of Alameda, once collection commences, the collected medicine will be trucked to Kansas City, Missouri).[1] Putting aside for a

[1]Cook et al. "Life Cycle Comparison of Environmental Emissions from Unused Pharmaceutical Disposal Options." Environ Sci Technol. 2012 May 15;46(10):5535-41.

moment the societal and economic questions presented by industry-funded take-back, it is important to understand the regulatory and legal issues associated with such programs.

Principally, take-back programs, whether industry funded or not, are regulated by the U.S. Drug Enforcement Administration (DEA) if they collect, or may reasonably be expected to collect, controlled substances. The DEA Rules limit collectors to the following DEA-registered entities: (1) manufacturers; (2) distributors; (3) reverse distributors; (4) retail pharmacies; (5) narcotic treatment programs; and (6) hospitals and clinics with an on-site pharmacy.[2] These entities must modify their registrations with DEA to become authorized as collectors.[3] In addition, law enforcement may collect in the course of their official duties.[4] Each of these registered entities, however, may only collect at their registered facilities. So, for instance, a pharmaceutical manufacturer would only be able to place a kiosk it controlled at one of its own plants. In addition, it is important to note that DEA compliance is incumbent upon the take-back program participants, not just its funders. In other words, it will be the kiosk host sites that must carefully evaluate how and to what degree they want to participate and comply with DEA regulations since, ultimately, the responsibility to ensure compliance and monitor operations falls upon them. This is a reality that Alameda simply chose to ignore under its Ordinance and a reason that program has still not collected a single medicine. Also, the hosting of a kiosk in general carries a multitude of location-selection, security, logistical, and reporting obligations on the kiosk host himself – things that cannot be off-loaded on a program funder or coordinator.[5]

Further, like the program in Alameda, simply shifting the funding and coordination activities of a take-back program on to industry does not mitigate the responsibilities for compliance of the local pharmacies and law enforcement agencies who serve as hosts for these kiosks. In fact, the DEA rules prohibit the mitigation of a pharmacy's regulatory burden by having a distributor or other entity maintain the collection receptacle at the subject pharmacy for them.[6] In addition, any kiosk participant is prohibited from collecting Schedule I substances. It is likely inevitable that inadvertent collection of Schedule I substances will happen. Therefore, it is unclear whether a non-law enforcement site could ever be in compliance with federal law. While none of this is meant to demonstrate that an Alameda-style take-back program is unachievable, it explains why it is not so simple to "shift" the responsibility on to the pharmaceutical industry.

Drug Take-Back Programs Do Not Solve Environmental Concerns

Despite all the regulatory issues associated with take-back programs, the question still remains: what are these programs actually going to solve? Quite simply, these programs do not "solve" environmental concerns, given that the majority of trace pharmaceuticals found in the water supply come from patients taking and metabolizing their medicine, and such sites could become targets for drug diversion.

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[2] 21 C.F.R §§ 1300.01(b), 1317.30(a)(1), 1317.40(a).
[3] Id. at §§ 1301.51(b), 1317.40(a).
[4] Id. at §§ 1317.30(a)(2), 1317.35.
[5] *See, e.g.* 21 C.F.R. § 1317.75(e)(1) (stating that kiosks must be "securely fastened to a permanent structure so it cannot be moved); *and* 21 C.F.R. § 1317.75(g) (stating that "installation and removal of the inner liner of a [kiosk] shall be performed by or under the supervision of at least two employees of the [collector]' in addition to strict storage, security, and disposal obligations for the removed liner).
6 21 C.F.R § 1317.40(c)(2); *see also* 79 Fed. Reg. at 53535.

With respect to any potential environmental impact, the Food and Drug Administration even notes that the primary way pharmaceuticals get into the environment is from patients taking their medicine:

> "The main way drug residues enter water systems is by people taking medicines and then naturally passing them through their bodies," says Raanan Bloom, Ph.D., an environmental assessment expert at FDA. "Many drugs are not completely absorbed or metabolized by the body and can enter the environment after passing through wastewater treatment plants. ... While FDA and the Environmental Protection Agency take the concerns of flushing certain medicines in the environment seriously, there has been no indication of environmental effects due to flushing," says Bloom.[7]

PhRMA agrees with FDA that medicines should not be flushed, except medicines FDA recommends flushing[8] usually because of high abuse or diversion potential, and our in-home disposal guidance reflects this. However, the vast majority of pharmaceuticals in the environment are due to human and animal digestion of medicines, which will not be prevented by drug take-back programs. Conversely, such programs can have a negative impact on the environment due to the large carbon footprint of these programs.

Specifically, Cook et al.[9] evaluated the effects of unused medicine disposed in the household trash versus collection programs and found that "A 100% trash disposal program would have similar API [active pharmaceutical ingredient] emissions to a take-back program with 50% participation, while also having significantly lower non-API emissions, lower financial costs, higher convenience, and higher compliance rates." This means that trash disposal conserves excess carbon emissions while keeping local government and consumer costs down.

In addition, PhRMA member companies have conducted research that evaluated whether detectable levels of pharmaceuticals in the environment pose a risk to human health, evaluated methods for the effective disposal of human medicines, and they continue to study the potential effects of human pharmaceuticals and their metabolites in surface waters on aquatic life. Additionally, many independent technical experts have contributed to the on-going scientific research in the area of pharmaceuticals in water. The studies conducted to date, published in peer-reviewed journals, which include work on sensitive subpopulations, suggest that it is highly unlikely that the very small quantities of pharmaceuticals detected in the environment would be harmful to human health. [10,11.12,13]

Take-back Programs Are Not the Solution to Reduce Prescription Drug Abuse.

At times, take-back programs are referenced as "the answer" to reducing prescription drug abuse. The rationale is that if families removed unused medicines from the medicine cabinet, it is less likely to be diverted. However, the issue is more complex because doctor shopping and the behavior of sharing

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[7]http://www.fda.gov/ForConsumers/ConsumerUpdates/ucm101653.htm
[8]http://www.fda.gov/ForConsumers/ConsumerUpdates/ucm101653.htm
[9]Cook et al. "Life Cycle Comparison of Environmental Emissions from Unused Pharmaceutical Disposal Options> *Environ Sci Technol.* 2012 May 15;46(10):5535-41.
[10]Christensen, F.M. *Pharmaceuticals in the environment – A Human Risk?,* Reg. Toxicol. & Pharmacol., 28, 212-221. (1998)
[11]Schwab, et al. *Human pharmaceuticals in US surface waters: A human health risk assessment.* Regulatory Toxicology and Pharmacology, Volume 42, Issue 3, *Pages 296-312* (August, 2005)
[12]Webb, et al. *Indirect human exposure to pharmaceuticals via drinking water,* Toxicology Letters, 142, 157-167. (2003)
[13]Mons, M.N., *Pharmaceuticals and drinking water supply in the Netherlands*, Kiwa N.V. Water Research. (2003)

personal medications, both currently being used and those that may be unused, with family and friends are also a factor in how people access prescription medicines. Take-back programs cannot address the abuse and misuse of drugs currently being used in the home, nor the other aforementioned behaviors associated with obtaining medicines for abuse. PhRMA is concerned that drug take-back programs could inadvertently create a greater potential for drug diversion through theft or misappropriation of collected medicines. Instead, simply disposing of medicines in household trash, as we discuss below, can ensure that unused medicines are not collected in one place to increase the opportunity for diversion.

Law enforcement and DEA play an important role in preventing diversion of drugs and potential abuse. The DEA, FDA, and pharmaceutical manufacturers have worked together to create plans for preventing the diversion of drugs that are susceptible to abuse. PhRMA also works with several partners on the issue of drug abuse and misuse, including the National Governors' Association (NGA), Association of State and Territorial Health Agencies (ASTHO), Community Antidrug Coalitions of America (CADCA), DrugFree.Org, and other groups on both the state and federal level. For example, over the past two years, NGA staff and Policy Academy partners worked with eleven different states and their teams of senior-level policymakers to develop tools for reducing prescription drug abuse. The teams, including governors' health and criminal justice advisors, state health officials, attorneys general, state chief information officers, legislators, physicians and health professional groups, examined a variety of ways to prevent abuse of medicine. The results were published in a document that provides best practices and guidance to Governors as to how they can best approach prescription drug abuse in their states.

PhRMA has worked with Partnership for Drug Free Kids[14] (formerly, A Partnership for a Drug Free America) on several projects. Recently, PhRMA helped fund and organize the "Wake up to Medicine Abuse" campaign. This public awareness campaign brought together the public and private sectors in a national education effort and call to action to curb the abuse of medicine. The campaign encourages and helps parents and the public-at-large to take action: first, by talking with kids about the dangers of abusing prescription and over-the-counter medicines, and second, by safeguarding and properly disposing of unused medications.

In addition, PhRMA is working with United States Attorneys and Attorneys General in several states to develop plans to educate patients, parents and young people about the risks associated with abuse of prescription drugs, through participation in state prescription drug abuse summits.

Finally, it is essential that prescription drug abuse education is incorporated into the work of multiple stakeholders. Prescribers, physicians but also dentists, nurse practitioners, and others with prescribing authority, must talk with their patients about the importance of taking medications exactly as prescribed and ensuring they are not prescribing more than the patient needs. Parents and educators should talk about the dangers of misuse and abuse of prescription medicines to children at an early age and continue open dialogue throughout high school. Other efforts, such as prescription drug monitoring program interoperability, developing abuse deterrent formulations for medicines and other efforts can help contribute to the effort to reduce the prevalence of prescription drug abuse. Unfortunately, there is not a silver bullet solution to prescription drug abuse, therefore, a multi-pronged approach, incorporating all stakeholders, must be utilized.

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[14] Drugfree.org

Research Demonstrates that Household Trash Disposal Is Effective for Disposing of Unused Medicines.

Past guidance advised patients to flush unused medicines to ensure that unused medicines were quickly disposed of to prevent accidental poisonings, misuse, and abuse of medicines. However, Tischler et al. concludes that household trash disposal and take-back for incineration are equally effective at removing the unused medicine contribution to pharmaceuticals in water.[15] Specifically, the paper found that if all unused medicines were placed in household trash and disposed of in municipal landfills, less than 0.1% of the total amount of medicine found in the environment would be contributed from landfills — the rest would be from patient use of medicine. Using current household trash disposal methods for unused medicines does not require the creation of a new, unnecessary infrastructure or the outlay of additional energy for special unused medicine collection.

PhRMA views "in-home" disposal of unused prescription medicines via the household trash as the most efficient and environmentally friendly method for disposal of unused post-consumer medicines. This approach which includes simple, easy to follow steps, is likely to contribute to consumers actually throwing out unused medicines. It does not require consumers to retain unused pharmaceuticals until a scheduled take-back day, look up that location and make a special trip, or to otherwise modify one's regular routine to transport unused pharmaceuticals to a collection location. Because household trash is generally picked up at least once a week, this approach would be incorporated into consumer's regular routine, contributing to increased compliance rates. Furthermore, the costs of implementation are nominal compared to other disposal approaches.

"In-home" disposal effectively manages potential environmental issues by ensuring that the medicines will either be incinerated or disposed of in landfills which will effectively isolate waste from the physical environment without creating the excessive carbon footprint associated with a take-back program. In-home disposal also avoids the re-concentration of pharmaceutical products inherent in any take-back program that poses a very real risk of theft, diversion, and improper use. A major concern with take-back programs is the environmental impact and cost of trips to a collection site or shipping the collected pharmaceuticals for destruction separately.

Given the results of scientific study in this area, PhRMA does not believe that unnecessary costs should be added to the healthcare system by mandating manufacturers to create a program that has more carbon emissions than trash disposal, does not benefit the environment because most pharmaceuticals enter the environment because patients take their medicine and do not fully metabolize it. In addition, PhRMA's members cannot establish kiosks in the community and any DEA-authorized host of a kiosk would need to assume the liability associated with any program.

Secure Disposal

PhRMA believes that any stakeholder approach in Los Angeles County should focus on educating patients on how to securely dispose of unused medicines. A potential model for the county could be

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[15]Tischler, et al. *Lanfill Disposal of Unused Medicines Reduces Surface Water Releases.* Integr Environ Assess Manag., Vol 9, No. 1, 142-154 (2012).

PhRMA's "My Old Meds"[16] Program which we have piloted in New York. This program instructs patients on how to safely dispose of medicine in the home or where to find current take-back programs in their community. To safely dispose of medicines in the home, PhRMA recommends these easy steps:

Step 1: Pour medication into a sealable plastic bag. If the medication is in solid form (pill, liquid capsule, etc.), add water to dissolve it.

Step 2: Add kitty litter, sawdust, coffee grounds or another mixing material to the plastic bag to make the solution less appealing for pets and children.

Step 3: Seal the plastic bag and put it in the trash.

Step 4: Remove and destroy all identifying personal information (for example, the prescription label) from the medication containers before recycling them or throwing them away. This helps to ensure medical privacy.

In conclusion, PhRMA recommends that the County study further and conduct thorough stakeholder discussions on the issue of secure drug disposal to fully understand all of the associated complexities. Especially because take-back programs are complex to implement and can serve as a location for the diversion of controlled drugs, these discussions should occur before the County drafts an ordinance so that the County and its stakeholders can determine the best path forward. We also encourage Los Angeles County to focus their efforts on promoting adherence to medication treatment regimens and educating their constituents on the safe disposal of unused medicines.

Please do not hesitate to contact me with any questions.

Sincerely,

John A. Murphy, III
202-835-3569 | JMurphy@phrma.org

[16] Myoldmeds.com